

Remarks

Claims 33-66 remain pending in the application. Independent claims 33, 39, 46, 49 and 57 have been amended to clarify that the transparent window area is defined by a surrounding non-transparent area. Claim 39 has also been amended to clarify that several, but not necessarily all, of the plurality of test tapes may be affixed to the slide. Support for these amendments can be found in the originally filed application and drawings, thus Applicant believes that the amendments add no new matter to the application.

Examiner rejected claims 33, 36-38, 42, 44, 45 and 62-64 under 35 USC 102 (e) as anticipated by US patent 6,447,463 to Borkowski. Borkowski shows an infection diagnosis kit. As applied to claim 33, Borkowski does not teach the concept of a kit for taking environmental samples as disclosed and claimed. Borkowski teaches a diagnostic kit for taking samples from the human body. Borkowski states the purpose is “for transferring one or more skin lesions to a remote location”.

An environmental test kit is intended to sample “the circumstances, objects, or conditions by which one is surrounded.” [Webster’s 9th Collegiate Dictionary] The claimant’s device is used to sample a wide variety of environmental surfaces such as wood, insulation, furnace filters, supply and return air registers, ceilings, walls, floors, inside cabinets, clothes, carpet backing, dust on furniture, window sills, and curtains.

The difference between a human body diagnostic kit and an environmental test kit becomes important in many of the further distinctions between the device as claimed and disclosed.

Manually recording information on the tape

Borkowski fails to show a space on the test tape to manually record information as disclosed and claimed in claim 33. This difference is important because, unlike sampling a person who can be moved into a position to allow convenient sampling, the device is an environmental test kit for use in spaces where sampling is often awkward and difficult. Contamination (by coming into contact with the user or areas other than sample area intended) is much more likely, and the user may not be able to (or would not want to) take the whole kit -- for example when the user is lying on his back in a crawl space under a house. The present invention allows the user to take only the tapes (on the backing) to use at the desired location and to manually record information on the tape concerning the sample site such that confusion later can be avoided. With the proposed use of the diagnostic kit of Borkowski, (i.e., a patient in a doctor's office room), the user is much less likely to experience confusion as to where the sample was taken from. Examiner correctly points out that Borkowski discloses a data form to be completed by user but this data form is not part of the test tape as disclosed and claimed.

Manually writing information about the site tested onto the tape strip means this information cannot become separated from the test sample making later analysis quicker and foolproof. This is especially important when multiple samples are taken sequentially in a remote location (e.g., an attic or crawl space) and the sample form is left behind because it is too cumbersome or awkward to handle in that location; the needed information can be immediately recorded in the appropriate area on the tape strip thus alleviating the burden of assigning it to memory.

Tape on a backing separate from the slide

Borkowski fails to show a test tape as disclosed and claimed in claim 33 that is separate from the slide. The tapes used for sampling with this device are stored on a backing and

only attached to the slide after collection of the sample. Examiner correctly points out that Borkowski shows the use of SCOTCH tape during concept preliminary experimentation described in column 4 of the patent. But in this respect the patent is vague, it is not clear from reading the passage how the experiment was performed. It is clear that SCOTCH tape does not have a window and that the testing intent was to study the diagnostic effectiveness of the process. It is unclear if the test tapes were in fact separate from the slide at the time of testing, this is an assumption that may or may not be true. Borkowski says (column 4 line 26) 'the tape fragments were than [sic] attached'. It might be assumed that this means that the tape fragments had to be separate but this is not true, Borkowski uses the term 'reattached' (column 4 line 7) in reference to figure 12 where the tape was never separate from the slide. So Borkowski fails to show a separate test tape in his kit as disclosed and claimed in claim 33.

Using an unattached tape strip (not attached to a placard or slide as disclosed by Borkowski) has important benefits when taking environmental samples as it allows maximum flexibility and maneuverability. Environmental surfaces can be uneven or rough, can have very narrow openings or be difficult to access (e.g., an ornate picture frame, the angled louvers of a supply air register, or a wall next to a clothes dryer).

Sample Window: Transparency

Borkowski discloses a tape having a central translucent window. Borkowski, however, does not suggest that remaining portions of the tape are not also translucent. By contrast, claim 33 of the present application requires that the tape is transparent only at the window area so it is very clear to the user where the sample must be placed. This limits the sample area that needs to be examined, which is time saving when doing microscopic work on environmental samples (discussed below). It also provides a clearly limited sampling area such

that the clients are not tempted to submit overly abundant samples (or samples taken from two or more different sites) with the hope that extra will be read for the same fee as one normal sample.

Placard to transport the slide

As applied to claim 36, Borkowski fails to show a placard having a slide storage area and adapted to releasably retain the slide as disclosed and claimed in claim 36. The placard provides a superior way to return the slide compared to dropping the slide loose in a sample bag as indicated by Borkowski.

Placard alignment indicia

As applied to claim 37, Borkowski fails to show preprinted alignment indicia within the slide storage area on the placard that is visible through the transparent slide. This is particularly relevant in the situation where multiple sample tapes are applied to a single slide as disclosed by this inventor. The correct placement of the slide sample tapes speeds handling and examination when it is time for the laboratory to analyze the sample under a microscope.

Unclear items

Examiner's handling of claims 42, 44, 45, and 62 -64 is unclear since they depend from claim 39 or claim 57 not rejected under Borkowski alone.

Claims 35 and 47 are rejected under 35 USC 103 (a) as unpatentable over Borkowski in view of Lorinez 5,812,312. Lorinez is used to show a grid that is not claimed in claim 35 or 47 so this basis of rejection is very unclear. Claim 35 depends from 33 and 34 and includes the limitation of instructions on the backing material. None of the references cited by examiner show a backing material or instructions on a backing material from which the test tapes are to be removed as disclosed and claimed. Claim 47 adds the limitation of a curved edge on the test tapes to make them easier to lift from the tape backing, especially when wearing safety

gloves during sampling; this feature is not shown in any reference. Claims 48 and 66 depending from claims 46 and 57 contain the limitation of a grid. Examiner may have intended to apply this combination to claims 48 and 66, responding to that possibility there must be a teaching that would suggest adding the grid of Lorinez to the slide of Borkowski. Examiner suggests it would be obvious to aid the Borkowski user in determining the size of the sample as well as in quantifying the sample. The purpose of Borkowski is diagnostic. According to column 2 line 47-50 the kit detects the presence or absence of fungal skin infection. Borkowski is silent on the size or on quantifying the sample, Borkowski simply provides a yes or no answer as to the presence of fungal infection thus it would not have been obvious to add the grid of Lorinez to the Borkowski tape without the teaching of applicant.

Claims 34, 39-41, 43, 46 and 48-61

Claims 34, 39-41, 43, 46 and 48-61 were rejected under 35 USC 103 (a) as unpatentable over Borkowski in view of Clayton et al 5,582,298. Clayton discloses a business form including a duplicate sample kit (one for testing, one for archiving). Clayton fails to disclose test tapes or multiple samples from multiple test sites. The Clayton device teaches adhesive 40 covered by wax paper release liner 60. A user peels off the liner 60 and attaches hair to the adhesive 40 such that the hair extends into windows 30, 32. The user then folds the card along lines 20 and 22 sealing the hair into the placard. The adhesive 40 holds the hair in place and holds the folded card closed on the hair but there is no test tape. So examiner's statement that test tapes are attached in the areas designated is not true because there is no test tape.

Tapes affixed to a backing

Clayton fails to show separate test tapes as disclosed and claimed in 33.

Therefore, Clayton fails to show a test tape that is releasably affixed to a backing as claimed in

34. Borkowski shows a tape attached to a slide and therefore Borkowski also fails to show a test tape that is releasably affixed to a backing as claimed in 34.

Having the tapes on a separate backing enables the tester to utilize the tapes themselves without the rest of the kit. The backing also is a means to instruct the sampler on proper usage of the test tapes to get a good sample. This increases reliability of the test and makes it user-friendly.

Plurality of tapes on one slide

Clayton fails to show test tapes and fails to show a slide, therefore it is not possible for Clayton to disclose **multiple** test tapes on **one** slide. Borkowski shows one test tape affixed to and covering one slide and therefore is not consistent with multiple test tapes on the same slide. Therefore, Clayton and Borkowski separately or together fail to show a slide configured to enable a plurality of test tapes to be affixed to one slide as disclosed and claimed in 39.

Alignment of multiple tapes on the slide

Clayton and Borkowski fail to show affixing multiple test tapes to one slide such that said transparent windows are aligned side by side as disclosed and claimed in 40. Clayton does teach side by side duplicate samples: "It is also desirable to 'archive' samples. That is to say duplicate samples are taken with one being analyzed and one being stored in the examining organization for subsequent analysis if it becomes necessary for any reason." There is no clear teaching of multiple tapes from multiple environmental sources on a single slide except applicant's disclosure.

The alignment of the tape windows in a single row allows reading of the multiple tape samples in a sequential manner without having to rearrange the position of the slide on the microscope stage. This increases efficiency (speed) of analysis. The placard has underlying illustrations showing the correct placement (alignment) of the tape strip sample(s).

Standardization

Neither Clayton nor Borkowski speak to the necessity of standardizing the transparent viewing area for practical use with a microscope, as set forth in Claim 41. The location of the window on every tape must be consistent to allow efficient reading of the multiple samples in a sequential manner without having to rearrange the position of the slide on the microscope stage. This increases efficiency (speed) of analysis.

The standardization of the size of the sample area (window) is also extremely important to the development of a consistent method for obtaining environmental surface samples for microscopic analysis. Eliminating the variable related to the size (quantity) of the sample “window” allows inter-lab comparisons of what is and is not considered normal content in an environmental sample. It allows all users (environmental testers) to test in a consistent manner with a procedure that minimizes the chance of contamination by the user or to the user, with a procedure that allows safe transport of the sample material (which may be hazardous) in the mail to the lab, with a procedure that is user friendly and convenient, and with a procedure that is efficient and favored by laboratory analysts.

Claims 43 and 44

Clayton and Borkowski separately or together fail to show a slide storage area on a placard adapted to releasably retain the slide on the placard as disclosed and claimed in 43. Borkowski teaches a slide but no placard and Clayton teaches a one piece placard including

sample areas, but no slide. There is no releasably retained slide in Clayton or Borkowski. Also Borkowski and Clayton fail to show pre-printed alignment indicia visible through said slide when the slide is retained as disclosed and claimed in claim 44. These features help to make the kit practical for environmental testing. The kit of Clayton et al like the kit of Borkowski is significantly different from the claimed device, as it is designed for the user to bring the sample to the kit instead of taking the test tapes to the sample site for collection.

Test Tapes

Inventor's claim 46 is a standardized device adapted for environmental testing and microscopic examination and is significantly different than the device disclosed in Borkowski.

Inventor's device discloses a limited transparent window that is "less than $\frac{1}{2}$ the area of said test tape". It directs the sampler to put the sample into a limited space, which means the microscopist can examine the entire viewing area within a reasonable amount of time at 400 to 1000 times magnification. In order to examine the area taught by Borkowski, it could take a microscopist many, many hours. This is impractical, inefficient, and counterproductive in environmental sampling. Additionally, if the sample deposit is sparse, it may be so difficult to find it in such a large space that it is missed by the microscopist altogether. This invention teaches an adequate space between the handling end and the sampling end of the test tape in order to avoid contamination of the sampling area (through coming into contact with the user or areas other than area intended).

Neither Clayton nor Borkowski teaches manually recording information directly on the sample tape. This feature is important as it enables the user to immediately record the sampled information when sampling in a challenging or awkward location, as explained above.

This feature alleviates the need to assign the information to memory until the placard can be filled out later.

Borkowski does not teach a handling end with pre-printed indicia instructing the user on where to handle the test tape. This helps to make the device user friendly and prevents the user from contaminating the sample area or being contaminated by the sample area. It also allows greater manipulation and management of the test tape--- for example when testing in narrow spaces, when sliding it along a surface to pick up environmental dust, or when needing an extended reach to sample a desired area.

Claim 48

As applied to claim 48, see above discussion relating to the combination of Borkowski in view of Lorinez.

The test kits

In Claims 46, 49, 57 and 63, Borkowski fails to teach multiple test tapes and a placard, as stated by examiner. Clayton does not teach test tapes or slides, only a placard that is distinguishable from inventor's placard. As stated above, Borkowski fails to show a transparent window less than one-half the area of the test tape as claimed in 46, 49, and 63. Also as stated above, Borkowski fails to show a non-transparent handling area with pre-printed indicia and upon which user may manually record information as disclosed and claimed in 46 and 49.

Borkowski also fails to show a non-transparent area positioned between the transparent window and a handling end as disclosed and claimed in 46. Borkowski also fails to show a backing upon which the test tape is releasably affixed, a slide separate from the test tape, a placard having a slide storage area, and pre-printed alignment indicia on the placard as claimed in 49 and 57.

Other

As applied to claim 48, see above discussion relating to the combination of Borkowski in view of Lorinez.

Borkowski and Clayton fail to teach a slot cut in the placard for insertion of a portion of the slide which allows the slide to be releasably attached to the placard, as disclosed and claimed in claims 51 and 58.

As previously discussed, under claim 46, Borkowski and Clayton fail to show an area for manually entered information between the window area and a handling tab, as disclosed in claims 54 and 61

As previously discussed under 46, Borkowski and Clayton fail to show the tab having handling instructions as disclosed in claims 55 and 62.

As previously discussed Borkowski in view of Clayton fails to show a curved edge on the test tape as disclosed in claim 56.

Examiner does not appear to have presented a treatment of claims 65 and 66. Claim 65 depends from claim 57 and provides the further limitation of the test tape having a curved end which is not shown in any reference. Claim 66 provides the limitation of the grid which was discussed above under the combination of Borkowski in view of Lorinez.

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In view of the foregoing amendments and remarks, it is respectfully submitted that the claims are now in condition for allowance and eventual issuance, and such action is respectfully requested. Should the Examiner have any further questions or comments that need be addressed in order to obtain allowance, he is invited to contact the undersigned attorney at the number listed below.

Acknowledgement of receipt is respectfully requested.

Respectfully submitted,

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